

PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 FEB 2005


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| Applicant's or agent's file reference 503518 DJJ | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/NZ2004/000069 | International filing date (day/month/year) 5 April 2004 | Priority date (day/month/year) 3 April 2003 | |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61F 2/44 2/30 | | | |
| Applicant ENZTEC LIMITED et al | | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> Box No. VIII | Certain observations on the international application |

| | |
|---|---|
| Date of submission of the demand 7 October 2004 | Date of completion of the report 23 February 2005 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer  DAVID MELHUISE Telephone No. (02) 6283 2426 |

Box No. I **Basis of the report**

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☒ the international application as originally filed/furnished

☐ the description:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ the drawings:

pages as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | |
|-------------------------------|----------------------|-----|
| Novelty (N) | Claims 5 | YES |
| | Claims 1 - 4, 6 - 11 | NO |
| Inventive step (IS) | Claims | YES |
| | Claims 1 - 11 | NO |
| Industrial applicability (IA) | Claims 1 - 11 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)**NOVELTY (N) Claims 1-4, 6-11:**

D1 - WO 2000/035382 A1

D2 - US 6527804 A

D3 - US 5002576 A

D4 - US 6419704 B1

D4 discloses the features of claims 1 to 4 and 8 to 11. Figures 5C or 7 for example show space confinement housings that are inflated with air, gas, liquid, oil, saline, elastomer or gel materials to make a compressible intervertebral disc. The upper and lower surfaces of the disk may move relatively towards each other and/or angle relative to each other. The maximum separation of the upper and lower surfaces is limited by panels attached to adjacent vertebrae as shown in figures 4F to 4H. These panels may be metal, nylon mesh or cloth fabric. See column 7 lines 29 to 50 of D4.

D1 to D3 each disclose the features of claims 1 to 3 and 6 to 10. For example, D1 shows in figure 1 a housing comprised of end plates 4 and bellows 10. Within this housing is a compressible fluid 12 and a compressible body 14. The plates 4 can incline relative to each other or move towards each other. See column 3 lines 26 to 37.

INVENTIVE STEP (IS) Claims 1-11:

D5 - US 6248106 B1

D6 - US 6063121 A

D7 - US 4759769 A

Claims 1-4, 6-11: As per novelty above.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 1 is not fully supported by the description because it is not restricted to an intervertebral disc, to which the description is directed.
2. Claim 7 lacks clarity because the scope of "an adaption of" (lines 1-2) is not clear. It is unclear how much the housing can be adapted and still be within the scope of the claim.
3. Claim 10 lacks clarity because it is not clear whether the features in brackets are defined in the claim or not. For example, the last five lines of the claim are in brackets and it is unclear whether these features in the brackets are meant to be considered the same as the feature defined on line 3 of the claim which has "(if necessary)" preceding it, or whether they are meant to be considered in some other way.
4. Claims 5 at lines 4-5 and claim 10 at lines 8-9 lack clarity because there is a bracket missing from somewhere in these lines.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Box V**

Claims 4, 5, 11: D5 to D7 each disclose means for limiting the maximum separation of the top and bottom surfaces or for limiting the motion of the housing. D5 shows in Figure 1A cables attached to adjacent vertebrae to restrict the relative movement of the vertebrae, D6 shows wires 94 as part of the prosthesis itself which limit the maximum separation of the plates, while D7 shows in figures 9 and 10 cables 110 which limit the maximum opening of the prosthesis. The wires of D6 are not disclosed as for limiting the separation of the upper and lower plates of the prosthesis, but nevertheless they do perform this function. Limiting the motion of a prosthetic intervertebral disc is considered to be a feature well known in the art. Therefore using the motion limiting features found in D5 to D7 with any of the discs disclosed in D1 to D4 is not considered to be inventive. I consider that this difference between the claimed invention and the citation constitutes no more than a mere workshop improvement. It is an arrangement that any competent worker in the art would be expected to make directly and without difficulty and by routine steps alone. Therefore the claimed invention does not involve an inventive step. D5 discloses the motion limiting features of claims 4 and 11, while D6 and D7 disclose the motion limiting features of claims 4, 5 and 11.

Claims 6, 7: D4 does not disclose the bellows shape defined in these claims. However a bellows shape is considered to be well known in the art and therefore its inclusion does not render claims 6 and 7 novel.